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Ms. Sylvie Dupont,
Secretary of the Board,
Patented Medicine Prices Review Board
Box L40, Standard Life Centre
333 Laurier Avenue West, 14th Floor
Ottawa, Ontario
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4626-5-4

Re: PMPRB Notice and Comment
Price Increases for Patented Medicines: Discussion Paper

Dear Ms. Dupont,

The PMPRB has requested comments on its Excessive Price Guidelines as they relate to allowable price increases for patented medicines. Specifically, stakeholders have been asked to respond to questions in the context of the following three framework scenarios:

1. Current system where patentees are allowed to take an automatic price increase in a given period up to a predetermined maximum, with price reviews taking place after the fact.
2. Patentees would be required to apply to the PMPRB in advance of any price increase, allowing a review of the proposed price increase before it is implemented to ensure that the new price is within the Guidelines.
3. Patentees would be required to apply in advance for a price increase and would also be required to provide justification for the proposed increase and the extent of the increase. The PMPRB would make a determination on both the appropriateness of the increase and on the extent of the increase up to a non-excessive maximum.

Through the provision of this document, Serono Canada Inc. is pleased to offer its response to the above noted discussion paper. First, however, we would like to provide our overall comments on the PMPRB's current Guidelines governing price increases for patented medicines and on the perceived need for changes to these Guidelines. In issuing the Notice and Comment document, the PMPRB points to concern over recent increases in some pharmaceutical prices, concern for provincial drug plan budgets and recent actions in other countries in relation to pharmaceutical prices as some of the reasons for questioning the continued appropriateness of the Guidelines relating to allowable price increases.

The fact that price changes for patented medicines, as measured by the PMPRB's Patented Medicine Price Index (PMPI), have consistently tracked well below changes in the Consumer Price Index (CPI) in all but one year since 1988 and below other pharmaceutical price indices (i.e. IPPI Pharma and US PPI Pharma) provides clear evidence that the current Guidelines, combined with provincial control systems, are effective. In addition, it is important to remember that many companies have elected not to take price increases, when in fact they could, as these increases could not be implemented at a provincial level due to the risk of de-listing. The PMPRB has for many years taken every opportunity to express its satisfaction over the effectiveness of its guidelines, the most recent being from the PMPRB's former Chairperson, Dr.

Elgie, who characterized the evidence supporting the effectiveness of current price controls as "overwhelming" in a speech at a pharmaceutical conference held in Toronto in April 2005[1]. We find it curious, therefore, that the appropriateness of these Guidelines is suddenly questioned because, after many years with very few increases, some companies actually chose to implement allowable increases.

With regard to concern for drug plan budgets, we agree that managing reimbursement budgets is indeed challenging. Increased utilization of pharmaceuticals in recent years, in part the result of an aging population, represents an important factor affecting drug plan expenditures. However, Parliament created the PMPRB as a means of balancing strengthened patent protection (and thus support for innovation) afforded by revisions to the Patent Act with the need to ensure that the prices of medicines protected by these patents are not excessive. The PMPRB is not mandated by Parliament to ensure that the prices of patented medicines in Canada remain low or to put in place policies to control provincial drug plan budgets. As stated in the discussion paper,

> The PMPRB is a quasi-judicial tribunal that carries out its mandate independently of other bodies such as Health Canada, which approves drugs for safety and efficacy and public drug plans, which approve the listing of drugs on their respective formularies for reimbursement purposes.

Serono Canada completely agrees. Each of these bodies has an established and independent role based on the tools provided to them through legislation: the PMPRB to ensure that Canadians are not paying excessive prices for patented medicines as determined by pricing factors set out in the Patent Act; Health Canada to ensure the safety of Canadians by approving medicines based on safety and efficacy criteria; and public drug plans to list, not list or restrict medicines on their formularies or to enter into other agreements aimed at controlling drug plan expenditures while at the same time optimizing access to treatments for Canadians. In our opinion, the PMPRB's role as a quasi-judicial tribunal that must render decisions on excessive pricing by weighing the evidence submitted by all parties is compromised by a perception of bias if it establishes pricing policies and practices for the benefit of one group of stakeholders over another.

As the PMPRB notes, other countries, including some referenced by the PMPRB, have taken steps to strengthen their cost-containment efforts, including price cuts, changes to reimbursement lists, price freezes and offsetting price decreases. It is important to keep in mind that the regulations in these countries allow for the implementation of such measures. In Canada, while provincial governments have the legislated means to put in place many of these measures, such measures are not encompassed in the current legislation governing the powers of the PMPRB. However, the prices of medicines in other countries are referenced by the PMPRB and price ceilings are established on that basis. Thus, changes to prices as a result of measures put in place by these countries are already reflected in (and have the potential to impact on) the PMPRB's review of patented medicine prices in Canada.

The PMPRB's discussion paper poses five questions,

1. Should the PMPRB's Guidelines continue to allow for automatic (i.e. without prior approval) price increases?

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[1] Drug Price Controls: Maintaining the Balance. Notes for an address by Robert G. Elgie to the National Pharma Strategy Conference, Toronto, April 4, 2005.

2. Are there considerations other than, or in addition to, the CPI that should be used to review price increases?

3. How often should price increases occur? (e.g. every year, once every 3-5 years, only after a certain introductory period, when justified)
4. If justification is required, what criteria should be considered?
5. Given that the CPI is established in the *Patent Act* as a factor to be considered by the PMPRB, do you have any comments on its appropriate application in future Guidelines?

While our overall comments expressed earlier in this document address several of these questions collectively, we offer the following additional question-specific comments.

Price Increases (questions 1, 2 and 5)

The PMPRB's current Guidelines limit prices increases to changes in the CPI. In our opinion, it would be more relevant to ties price increases with an index that specifically applies to changes in direct costs of manufacturing our brands. If designing such an index were not possible, Serono would be willing to accept CPI as the limitation factor. The use of the term "automatic" in question 1 suggests that companies automatically implement allowable price increases each year. This, of course, is not the case since price increases on patented medicines have been within allowable limits and a relatively rare occurrence as they could not be actionable at a provincial level.

In our opinion, questioning the appropriateness of the current Guidelines limiting price increases is unjustified and implementing changes to them, unnecessary. As acknowledged on several occasions by the PMPRB, the current Guidelines, combined with provincial control systems and a competitive marketplace, are extremely effective at controlling the prices of patented medicines. In fact, even in years prior to 1994 when the CPI Guideline was less restrictive in that it allowed for the continuing accumulation of annual changes in the CPI, increases in patented medicine prices tracked below annual inflation in all but one year. This was also the case for changes in patented medicine prices as measured by the PMPI in comparison to the IPPI Pharma and the US PPI pharma prior to 1994. In addition, since the implementation of the International Price Guidelines in 1994, Canadian prices of patented medicines have tracked 5% to 12% lower than the median of international prices - a further indication of the effectiveness of the current Guidelines.

Generic Product Price Increases in Canada

The same cannot be said of the prices of generic products. In its report entitled "A Study of the Prices of the Top Selling Multiple source Medicines in Canada" published in November 2002, the PMPRB noted that the prices of generic products in Canada were between 21% and 51% above the median of international prices depending upon the source of US prices used. In addition, generic prices were 49% above the median when US prices were excluded from the comparison. In terms of price increases, unlike patented medicines, there are no restrictions of allowable increases in the price of generic products apart from the risk of de-listing by provincial formularies. Over the years, increases in the prices of some generic products have far exceeded the limits imposed on patented medicines by the PMPRB's CPI Guideline. For example, in December 2000 the price of Apo-imipramine 50 mg was increased from $0.023 per tablet to $0.081 per tablet with another increase to $0.3065 per tablet implemented in December 2001.[2]

[2] Manufacturers' list price history published by BC Pharmacare.

As a biotech company involved in costly research to develop new and innovative products for unmet medical needs, Serono finds it difficult to perceive of any possible justification for price increases of this magnitude by companies conducting limited research resulting in no new treatments. In our opinion, it is inappropriate for the PMPRB to be considering the implementation of more restrictive limits on an innovative industry already faced with significant regulatory and pricing restrictions when the generic industry is free to increase prices by any level and with no justification. We believe that the PMPRB's efforts regarding price increases would be better spent analyzing and reporting on cases of significant increases within the generic industry.

Prior Approvals for Price Increases (questions 3 and 4)

These two questions, in part, deal with the proposed requirement of providing justification for and receiving approval from the PMRPB for planned price increases. This approach will require the PMPRB to review and make rulings on planned price increases prior to their being implemented. In our opinion, there is no need to justify methods that mitigate the erosion of the value of our brands. Although the PMPRB is currently seeking to amend the *Patented Medicine Regulations* to require the provision of proposed prices for new medicines two months prior to launch and of proposed price increases in any market four months prior to implementation, there is no provision in the *Patent Act* that envisages a requirement for the routine collection by the PMPRB of patented medicine prices prior to their establishment in the marketplace, much less providing the PMPRB with the authority to review and rule on these prices in advance. The consistent reference throughout the Patent Act of the price at which a medicine is being or has been sold provides a very clear picture of the intent of Parliament with regard to the mandate of the PMPRB. Reference to the prices at which a medicine has been sold is particularly prominent in the pricing factors directing the PMPRB's decisions regarding excessive pricing. Thus, since the PMRPB has no authority to approve or reject price increases in advance of their implementation, requiring companies to file for approval, and provide justification, for planned price increases represents an unnecessary additional burden.

In summary, the PMPRB's current Guidelines are effective at controlling the prices of patented medicines in Canada. In our opinion, further restricting the allowable limits for price increases are unjustified. Requiring the notification and justification for planned price increases and the PMPRB's suggested prior approval approach for such increases represents an unnecessary additional burden on patentees. In addition, since there is no legislative authority allowing the PMPRB to approve or reject a planned price increase prior to its implementation, establishing guidelines, policies and practices in this regard goes beyond the PMPRB's current mandate.

Yours truly,

Deborah Brown
Regional Vice-President